K103155

OCT 28 2011

510(k) Summary

General Information

Classification	Class II
Trade Name	SuMO Access and Tissue Resection System
Submitter	Apollo Endosurgery, Inc. 7000 Bee Cave Road Suite 350 Austin, Texas 78746 Tel: (512) 328-9990
Contact	Greg Mathison
Date Prepared	October 28, 2011

Indications for Use

The **SuMO™ Access and Tissue Resection System** is intended to access, dissect, and resect soft tissue in endoscopic gastrointestinal procedures such as removal of flat polyps.

The **Injection Needle** is intended for endoscopic injection of solutions such as saline as a procedural aid in endoscopic procedures.

The **Tunneling Balloon** is intended for soft tissue separation and dilation during endoscopic procedures.

The **Dilation Balloon** is intended for soft tissue separation and dilation during endoscopic procedures.

The **Tissue Resection Tool** is intended for endoscopic resection in the gastrointestinal tract.

The **SuMO™ Snare** is intended to remove polyps and small tumors from the gastrointestinal tract.

Predicate Devices

K061222	Injectra Injection Needle	Medi-Globe Corp
K082114	Electrocautery Dilation Balloon	Apollo Endosurgery
K042412	Spacemaker Balloon	US Surgical
K943935	Polypectomy Snare	Medi-Globe Corp
K050578	Duette Muscosectomy	Cook

Device Description

The Apollo Endosurgery SuMO Access and Tissue Resection System is a single-use system intended to access, dissect, and resect soft tissue in endoscopic gastrointestinal procedures.

The system is comprised of five component devices:

- Injection Needle
- Tunneling Balloon
- Dilation Balloon
- Tissue Resection Tool
- SuMO Snare

Materials

All materials used in the manufacture of the SuMO Access and Tissue Resection System are suitable for this use and have been used in previously cleared products.

Apollo conducted GLP biocompatibility testing including:

- Cytotoxicity
- Sensitization
- Intracutaneous Toxicity

The materials were found to be biocompatible and suitable for this use.

Sterilization

The SuMO System is sterilized in a validated ETO cycle with a resulting SAL of 10^{-6}. ETO residual testing was conducted and met FDA and international requirements.

Testing

Product testing was completed and met the acceptance criteria. Testing was completed, including: dimensional, inflation/deflation, balloon size and reloading, resistivity and endoscope compatibility.

Electrical safety and electromagnetic compatibility testing was also performed with the products meeting the requirements of the test standards.

Summary of Substantial Equivalence

The SuMO Access and Tissue Resection System is equivalent to the features of the predicate products. The table below compares the basic attributes of the SuMO System with other legally marketed predicate devices.

Product Comparison Table

Feature/Information	**Apollo SuMO System**	**Predicate Devices**
FDA Classification	Class II	Class II
Regulation number	876.1500	876.1500
Materials	Biocompatible	Biocompatible
Endoscopic Use	Yes	Yes
Endoscope Compatibility	Same	Same
Needle Gauge	Same	Same
Working Length	Same	Same
Catheter Diameter	Same	Same
Electrocautery Type	Same	Same
Dilating Balloon	Same	Same
Provided Sterile	Same	Same
Method of Sterilization	Same	Same
Single Use	Same	Same
Packaging	Same	Same

Conclusion

The indications for use, basic overall function, clinical application, methods of manufacturing, and materials used are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Gregory Mathison
Vice President, Regulatory Affairs
Apollo Endosurgery, Inc.
7000 Bee Caves Rd., Suite 350
AUSTIN TX 78746

OCT 2 8 2011

Re: K103155
Trade/Device Name: Apollo SuMO Access and Tissue Resection System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: September 29, 2011
Received: October 4, 2011

Dear Mr. Mathison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103155

Device Name: Apollo SuMO Access and Tissue Resection System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal and Urological Devices
510(k) Number K103155